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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,222	02/27/2004	Qin Yu	UPN0003-100	9718

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EXAMINER

ROBINSON, HOPE A

ART UNIT PAPER NUMBER

1656

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/789,222

Applicant(s)

YU, QIN

Examiner

Hope A. Robinson

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-80 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Election/Restriction***

1. The following Restriction Requirement is set forth below as claims were inadvertently left off the previous communication and to clarify the record.
2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9, 19-in-part (as it pertains to the peptide)-22, 26-in-part-28, 53-54, 56-57-in part and 55, drawn to a pharmaceutical composition comprising the protein fragment, classified in class 530, subclass 300.
  - II. Claims 10-18, 19-in-part (as it pertains to the nucleic acid), 23-25, 26-in-part , 29-32, 53-54, 56-57-in part and 58-60 drawn to a pharmaceutical composition comprising the nucleic acid/vector, classified in class 435, subclass 6.
  - III. Claims 33-39, drawn to a methods of treatment of heart diseases or stroke or blood vessel blockage, classified in class 514, subclass 2+.
  - IV. Claims 40-52, drawn to a method of identifying compounds that modulate binding of Ang-1 to ECM, classified in class 435, subclass 7.1.
  - V. Claims 61-62, drawn to a method of treating an individual having cancer using the DNA, classified in class 435, subclass 44.
  - VI. Claim 63, drawn to a method of preventing diabetes, classified in class 514, subclass 12.
  - VII. Claims 64-66 and 75-77, drawn to a fusion protein, classified in class 424, subclass 192.1.

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VIII. Claims 67-68, drawn to a method of diagnosing, classified in class 435, subclass 6+.

IX. Claims 69-74, drawn to a method of inhibiting, classified in class 435, subclass 7.2.

X. Claims 78-80, drawn to a nucleic acids, classified in class 536, subclasses 23.1.

3. The claims of Inventions I-X are drawn to a multitude of amino acids, nucleic acids thereto and methods, which use these compounds. Each of the different proteins, nucleic acids, and methods of use are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. 121.

Upon election of one of Groups I-X, Applicant is additionally required to elect a single amino acid or nucleic acid. This requirement is not to be construed as a requirement for an election of species, since each of the compounds is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

4. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-II, VII and X are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group X is composed of nucleotides linked in phosphodiester bonds and arranged in spaced as a double helix. The fusion proteins of Group VII is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The composition of Group I

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comprises the Ang-1 protein without a fusion partner can be used as a medicament. In addition, Group II consists of a nucleic acid, said nucleic acid is in a composition and may not be the same nucleic acid encoding the fusion protein of Group VII. Furthermore, the products of Groups I-II, VII and X can be used in materially different processes, for example, the DNA of Group X can be used in hybridization assays, the protein can be used in the composition of Group I but can also be used to make fusion proteins with an enzymatic function or to make antibodies. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of I-II, VII and X are patentably distinct from each other. (See MPEP 806.04, MPEP 808.01, unrelated inventions).

Inventions III-VI and VIII-IX are patentably distinct having different method steps, end points and uses different products.

Inventions X and III-VI and VIII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP 806.04, MPEP 808.01). In the instant case the different inventions are directed to chemically different compounds, which can be made and used without each other. For example, the DNA can be used to make probes or primers.

Inventions VII and III-VI and VIII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product (MPEP § 806.05(h)). In the instant case the polypeptide could be used in an entirely different manner, such as in a method antibodies.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, the inventions have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference, which would anticipate the invention of one group, would not necessarily anticipate or make obvious the other group. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, election of a single group for examination purposes as indicated is proper.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

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Amendments submitted after final rejection is governed by 37 CFR 1.116; amendments submitted after allowance is governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between products claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 9, 2006

Hope A. Robinson, MS  
Examiner  
Art Unit 1653  
**HOPE ROBINSON**  
**PATENT EXAMINER**